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10/629,296	07/28/2003	Yasunori Kawate	11333/25	6488

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,296	KAWATE, YASUNORI	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12,14 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,14 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment with arguments filed on January 9, 2007, is acknowledged and has been entered. Claims 2, 3, 13, 15-17, and 26-32 have been cancelled. Claims 1, 4-12, 14, and 18-25 have been amended. Accordingly, claims 1, 4-12, 14, and 18-25 are pending are under examination.

Withdrawn Rejections

2. The rejections of claims 2, 3, and 15-17 are now moot in light of Applicant's cancellation of the claims.

3. In light of Applicant's argument, the rejection of claims 5, 6, 18, and 19 under 35 U.S.C. 102(b) as being anticipated by Shingo (JP B 19349) (Abstract), is hereby, withdrawn.

4. In light of Applicant's arguments, the rejection of claims 1, 5-11, 14, and 18-24 under 35 U.S.C. 102(b) as being anticipated by Oku et al. (US Patent 6,106,778), is hereby, withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to an analyzer comprising a sample preparing portion (for preparing an assay sample), a light source (for irradiating the assay sample), a light detector (for detecting optical information from blood cell morphology and binding interaction between carrier particle-immobilized binding partners and soluble analytes present in the sample that the binding partners are specific to), and an analyzing portion (for blood cell counting and analyzing immunological binding interactions between carrier particle-immobilized binding partners and soluble analytes present in the sample that bind the binding partners).

In the specification at page 2, lines 4-6, the analysis apparatus includes an automated hematology analyzer such as the Sysmex XE-2100 supplied by Sysmex Corporation. Other parameters measured by the analyzing portion of this hematology analyzer include mean corpuscular volume (MCV) which is a mean value of erythrocyte sizes in the blood sample, and hematocrit which is a measure of packed red cells occupying the blood sample (page 3, lines 4-13). The light source is a laser beam source such as a semiconductor laser beam source (page 13, lines 2-3 and page 25, lines 3-4). The light detector includes photomultiplier tubes and photo diodes (page 13, lines 4-11 and page 25, lines 7-16). The analyzing portion is a computer which includes a hard disk, CPU, ROM, RAM and the like (page 3, lines 14-16). At page 30, line 14 to

page 31, line 1 of the specification, Applicant specifically provides that the entire operation from the setting of the whole blood (in the sample preparing portion) to analysis (in the analyzing portion) of the apparatus are performed according to standard measurement method with an automated hematology analyzer XE-2100 which is supplied by Sysmex Corporation.

5. Claims 1, 4, 7, 9-12, 14, 20, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (US Patent 6,228,652).

Rodriguez et al. disclose an analyzer which comprises a sample preparing portion for subjecting samples to reagent, a light source (optical means) for irradiating the assay sample, light detectors for detecting a first optical information, i.e. radiation scattered, from irradiated blood cells and a second optical information, i.e. fluorescence, from fluorescence-labeled cell surface antigens in different subsets of cells. The analyzer further includes analyzing portions (1) for counting and differentiating between blood cell types and also (2) for determining concentration of different fluorescent-labeled cell surface antigens (assay substances) (see column 4, line 28 to column 5, line 18 and column 5, lines 34-47). The sample preparing portion is configured to subject a first and a second aliquot of samples (or a plurality of such aliquots) to different reagents. Rodriguez et al. teach subjecting each individual aliquot to different reagents such as fluorescent dyes and fluorescent-labeled monoclonal antibodies specific for the analyte (cell surface antigens: CD4 and CD8) to be assayed or specific for blood cell surface markers in order to stain different blood cells (see column 7, line

59 to column 8, line 20 and column 11, line 46 to column 12, line 2). The light source may be any one of continuous wave laser, argon-ion laser, and diode-pumped solid state laser (see column 9, lines 26-34, column 10, lines 44-56, and column 13, lines 43-53). The different light detectors are photodetectors that correspond to different fluorescence spectra by different dyes and fluorochromes (see column 8, lines 21-65 and column 10, line 57 to column 11, line 28). The analyzing portion counts and differentiates between erythrocytes (red cells), leucocytes (fluorescent labeled subsets of white cells), and platelets (see column 5, lines 18-28 and column 7, line 58 to column 8, line 20). The analyzing portion provides a measure of hematocrit value based on size information of blood cells (MCV and RBC). According to Rodriguez et al., the analyzing portion corrects immunoassay results, such as for hemoglobin, based on blood cell counting values (MCH and RBC) (see column 8, lines 49-60 and column 14, lines 5-40). Optical information that is measured includes scattered light and fluorescence intensity from the analyte.

Since the Rodriguez et al. disclose an analyzer having a sample preparing portion, a light source, a light detector, and an analyzing portion that are consonant to those recited in the claims, it is maintained that Rodriguez anticipates the claimed invention.

In as far as claim 9, which recites that the analyzing portion is used to correct a whole blood immunoassay result to a serum or plasma immunoassay result based on blood cell counting, a recitation of the intended functional use of the claimed analyzer must result in a structural difference between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of being configured to perform the intended use, then it meets the claim.

6. Claims 1, 8, 11, 14, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shingo (JP B 19349) (Abstract).

Shingo discloses an analyzer which comprises a sample preparing portion (reaction tank), a light source (semiconductor laser), a light detector (photodiode), and an analyzing portion (microcomputer). The sample preparing portion is configured to prepare a sample mixture by adding reagent to the sample. The reagent comprises carrier particles (polystyrene latex) having antibody or antigen immobilized thereto. Non-agglutinated single particles and agglutinated particles formed by the carrier particles in an immunoassay are differentiated by the analyzing portion according to their different optical information such as scattered light intensities and calculated rate of agglutination. See Abstract.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4, 7, 9, 10-12, 20, and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These issues encompass new grounds of rejection resulting from amendment of the claims by Applicant.

Claim 1, in lines 3-5, is vague and indefinite in reciting, "wherein the assay sample comprises a reagent and a whole blood specimen and wherein the reagent comprises carrier particles sensitized with an antibody or an antigen against a target substance in the blood specimen" because it is unclear how the assay sample and the reagent are part of the claimed analyzer. Reagents and samples are generally elements incorporated into an analyzer apparatus where they are subjected to an assay method; however, they are not deemed to be part of an apparatus.

Claim 1, in line 7, is vague and indefinite because it fails to specifically define what optical information from the assay sample is being detected by the light detector. As an example, is there fluorescence or light scattering from blood cells or light scattering resulting from binding interaction between the target substance in the sample and the antigen or antibody that are immobilized in the carrier particles, which provides optical information in the assay sample that can be differentially detected.

Claim 2 is vague and indefinite in reciting, "wherein the assay sample further comprises a second reagent comprising a fluorescent dye..." because it is unclear how the assay sample further comprising a second reagent, are part of the claimed analyzer. Reagents and samples are generally elements incorporated into an analyzer apparatus

where they are subjected to an assay method; however, they are not deemed to be part of an apparatus.

Claim 9 remains ambiguous in lacking clear antecedent basis for the recitation of, "a whole blood immunoassay result to a serum or plasma immunoassay result" because it remains unclear what is encompassed by the recitation of "an immunoassay result" since there does not appear to be an assay that is being performed using the instant claimed apparatus. Does Applicant intend to encompass a concentration value obtained from degree of agglutination which resulted from a binding interaction between the target substance present in the whole blood sample and the antigens or antibodies used to sensitize the carrier particles. See also claim 10.

Claim 11 remains vague and indefinite in reciting, "the optical information is scattered light from the assay sample" because it fails to specifically define what significant element in the assay sample the scattered light measurement, is being obtained from, i.e individual blood cells and degree of agglutination. As recited, the optical information would include scattered light from all elements in the assay sample including all unbound carrier particles, which does not appear to be what Applicant intends.

Claim 12 remains vague and indefinite in reciting, "the optical information is fluorescence from the assay sample" because it fails to specifically define what significant element in the assay sample the fluorescence measurement, is being obtained from, i.e individual blood cells and degree of agglutination. As recited, the

optical information would include fluorescence measurement from all elements in the assay sample including all unbound carrier particles, which does not appear to be what Applicant intends.

Claim 14, in line 13-19, is vague and indefinite because it fails to specifically define what optical information from the immunoassay sample and blood counting sample are being detected by the light detector and analyzed by the analyzing portion. As an example, is there fluorescence or light scattering from blood cells or light scattering resulting from binding interaction between the target substance in the sample and the antigen or antibody that are immobilized in the carrier particles, which provide optical information in the immunoassay sample and the blood counting sample that are differentially detected.

Claim 14, line 16, has improper antecedent basis in reciting, "a substance." Additionally, it is unclear what structural cooperative relationship between the recitation of "a substance" in line 16 and "a target substance" in line 8. See also claim 21.

Claim 22 remains ambiguous in lacking clear antecedent basis for the recitation of, "a whole blood immunoassay result to a serum or plasma immunoassay result" because it remains unclear what is encompassed by the recitation of "immunoassay result". Does Applicant intend to encompass a concentration value obtained from degree of agglutination which resulted from a binding interaction between the target substance present in the whole blood sample and the antigens or antibodies used to sensitize the carrier particles. See also claim 23.

Claim 24 remains vague and indefinite in reciting, "the optical information is scattered light from the immunoassay sample" because it fails to specifically define what significant element in the immunoassay sample the scattered light measurement, is being obtained from, i.e individual blood cells and degree of agglutination. As recited, the optical information would include scattered light from all elements in the assay sample including all unbound carrier particles, which does not appear to be what Applicant intends.

Claim 25 remains vague and indefinite in reciting, "the optical information is fluorescence from the immunoassay sample" because it fails to specifically define what significant element in the immunoassay sample the fluorescence measurement, is being obtained from, i.e individual blood cells and degree of agglutination. As recited, the optical information would include fluorescence measurement from all elements in the assay sample including all unbound carrier particles, which does not appear to be what Applicant intends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 4-12, 14, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oku et al. (US Patent 6,106,778) in view of Rodriguez et al. (US Patent 6,228,652).

Oku et al. disclose a compact combination blood cell count and immunoassay analyzer wherein the sample preparing portion is configured for preparation of split blood specimens, one for immunoassay section and the other for blood cell measuring section (see Abstract). The results of immunoassay, i.e. C-reactive protein (CRP), are corrected using a hematocrit value obtained by measurement of the number of blood cells (see column 1, line 62 to column 2, line 3 and 29-36; and column 7, lines 12-25). The analyzer in the immunoassay section comprises a light source (light irradiating section), a light detector (light detection section) for detecting optical information from the immunoassay, and an analyzing portion (microcomputer with processor) for performing arithmetic computation from the measured optical information from the binding information between anti-CRP antibody immobilized into carrier particles (latex

immunoreagent) that binds CRP protein present in the sample. The analyzer in the blood cell count section is configured to count and differentiate between leucocytes (WBC), erythrocytes (RBC), and platelets, and also to measure mean corpuscular volume (MCV) and hematocrit (Hct) using electric resistance. The analyzer in the blood cell count section also comprises a light source and a light detector for detecting optical information (absorption: light irradiation section) from hemoglobin in the sample, and an analyzing portion (microcomputer with processor) for performing arithmetic computation from the measured electrical resistance measurements and optical information (see column 4, lines 18-37 and column 5, lines 6-11).

Oku et al. differ from the instant invention in failing to teach that the light detector detects for optical information, i.e. light scatter and fluorescence from blood cells, and the analyzer portion analyzes the optical information for purposes of blood cell counting and differentiation.

Rodriguez et al. is discussed supra.

One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the light detector and analyzing portion as taught by Rodriguez, into the combined blood cell count and immunoassay analyzer as taught by Oku because Oku specifically provided advantage in being able to measure blood cell differentiation and target analyte concentration in a simultaneous manner in a whole blood sample such as in emergency diagnostic medicine, whereas Rodriguez specifically taught that using an analyzer having a single light detector and analyzing portion that can measure light scatter and fluorescence from particle combinations in a

sample, would also allow for simultaneous detection and analysis of light scatter and fluorescence measurements from blood cells and target analytes bound to carrier particles present in the whole blood sample.

Response to Arguments

9. Applicant's arguments with respect to Oku et al. as anticipating claims 1, 5-11, 14, and 18-24 have been considered but are moot in view of the new grounds of rejection.

10. Applicant's arguments filed on January 9, 2007 have been fully considered but they are not persuasive.

A) Applicant argues that Rodriguez et al. does not contain a teaching or suggestion of a sample preparing portion configured as required by amended claim 1 and amended claim 14; hence, the claims are neither anticipated by or nor would have been obvious in view of Rodriguez et al. Applicant specifically contends that claims 1 and 14 have been amended to require that the sample preparing portion is configured "for preparing an assay sample comprising a reagent that comprises carrier particles sensitized with an antibody or an antigen against a target substance in a whole blood sample," which is neither taught nor suggested by Rodriguez et al.

In response to applicant's argument that the Rodriguez reference does not teach or suggest the claimed invention because it does not provide a teaching or suggestion of sample preparing portion intended for "for preparing an assay sample comprising a

reagent that comprises carrier particles sensitized with an antibody or an antigen against a target substance in a whole blood sample," a recitation of the intended use of sample preparing portion of the claimed analyzer must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, claims 1 and 14 do not recite or define how the sample preparing portion of the analyzer is differentially and physically structured so as to be distinct from the sample preparing portion of Rodriguez et al. Accordingly, the rejection of 1, 4, 7, 9-12, 14, 20, and 22-25 under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al., is being maintained.

B) Applicant argues that Shingo describes an apparatus for analyzing serum and contains no teaching or suggestion of blood cells being contained in the serum sample. Applicant contends that the representation in the Examiner's Office Action of the non-agglutinated single particles as "blood cells" is not substantiated by the citation.

In response, Examiner concedes that the serum sample as used in the Shingo reference, does not include blood cells. Accordingly, the rejection of claims 5, 6, 18, and 19 as being anticipated by Shingo has been withdrawn.

C) Applicant argues that Shingo does not contain a teaching or suggestion of "an analyzing portion where blood cell counting ... is carried out ... based on optical

information detected by [a] light detector" as recited in claim 1 and claim 14; hence, the claims are neither anticipated by nor would have been obvious in view of Shingo.

In response to applicant's argument that the Shingo reference does not teach or suggest the claimed invention because it does not provide a teaching or suggestion of "an analyzing portion" intended for blood cell counting based on optical information detected by a light detector, a recitation of the intended use of the analyzing portion of the claimed analyzer must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, claims 1 and 14 do not recite or define how the analyzing portion of the claimed analyzer is differentially and physically structured so as to be configured to be distinct from the sample analyzing portion taught by Shingo. Accordingly, the rejection of claims 1, 8, 11, 14, 21, and 24 under 35 U.S.C. 102(b) as being anticipated by Shingo is being maintained.

11. For reasons aforementioned, no claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 3, 2007